

1481/65019-DA-PCT-US/JPW/AJM/CY

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Marc Feldmann and Ravinder N. Maini  
Serial No. : 09/754,004 Examiner: P. Gambel  
Filed : January 3, 2001 Group Art Unit: 1644  
For : TNF $\alpha$  ANTAGONISTS AND METHOTREXATE IN THE  
TREATMENT OF TNF-MEDIATED DISEASE

1185 Avenue of the Americas  
New York, New York 10036  
December 3, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Mail Stop RCE**

Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following disclosures, which are listed on Form PTO-1449 (**EXHIBIT A**). Copies of the disclosures listed below as items 1 and 2 are attached hereto as **EXHIBITS 1 and 2**.

1. Cronstein, et al., "Therapeutic Cocktails for Rheumatoid Arthritis: The Mixmaster's Guide", Arthritis & Rheumatism, 50(7):2041-2043 (2004) (**EXHIBIT 1**), and
2. Genovese, et al., "Combination Therapy with Etanercept and Anakinra in the Treatment of Patients with Rheumatoid Arthritis Failing

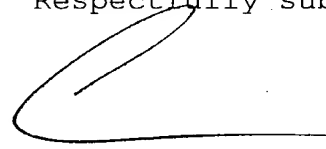
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Page 2

Methotrexate", Arthritis & Rheumatism,  
50(5):1412-1419 (2004) (**EXHIBIT 2**).

If a telephone conference would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.


No fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if a fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Application Number 09/754,004	
		Filing Date		January 3, 2001	
		First Named Inventor		Marc Feldmann, et al.	
		Art Unit		1644	
		Examiner Name		P. Gambel	
		Attorney Docket No.		1455/65019-DA-PCT-US/JPW/AJM/CY	
<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	1	CRONSTEIN, et al., "Therapeutic Cocktails for Rheumatoid Arthritis: The Mixmaster's Guide", <u>Arthritis &amp; Rheumatism</u> , 50(7):2041-2043 (2004); and			
	2	GENOVESE, et al., "Combination Therapy with Etanercept and Anakinra in the Treatment of Patients with Rheumatoid Arthritis Failing Methotrexate", <u>Arthritis &amp; Rheumatism</u> , 50(5):1412-1419 (2004).			
EXAMINER SIGNATURE		DATE CONSIDERED			
<p>*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a checkmark here if English language Translation is attached.</p>					

Applicants: Feldmann, et al.  
U.S. Patent No. 09/754,004  
Issued: January 3, 2001  
**Exhibit A**